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(71) Applicant *(for all designated States except US)*: **TEVA MEDICAL INDUSTRIES LTD.** [IL/IL]; P.O. Box 2, 77100 Ashdod (IL).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **KRAUS, Menahem** [IL/IL]; 25 Pashosh Street, 76100 Rehovot (IL).

(74) Agents: **COLB, Sanford, T.** et al.: Sanford T. Colb & Co., P.O. Box 2273, 76122 Rehovot (IL).

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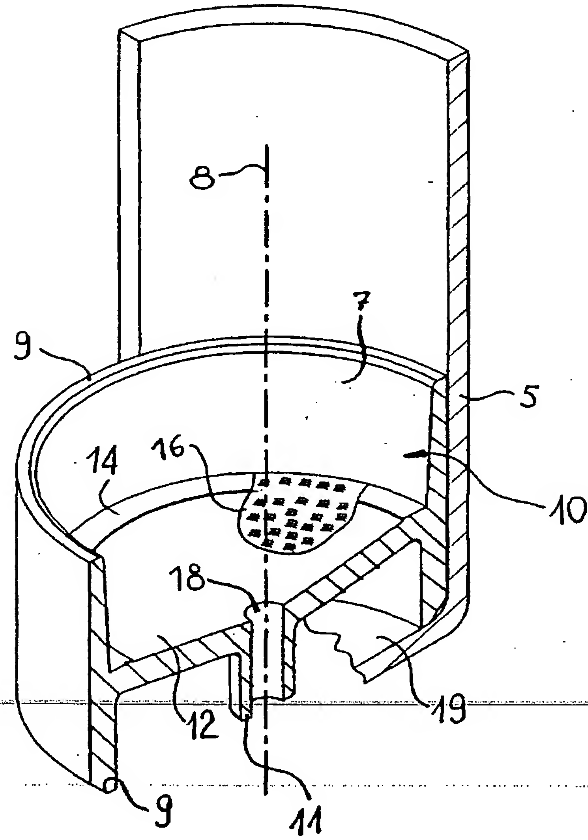
(54) Title: MEMBRANE SUPPORT FOR DRIP CHAMBER



(57) Abstract: A membrane support (10, 20) for assembly into a drip chamber (5), characterized by a support member (7) having a longitudinal axis (8, 27), two ends (9) and at least one support face distanced from both ends (9) and generally parallel to the longitudinal axis (8, 27), a membrane (16, 26) joined to the at least one the support face, and a support member outlet (11, 32) formed in the support member (7) and in fluid communication with the membrane (16, 26), the support member outlet (11, 32) being fluidly communicable with an outlet of a drip chamber (5).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

MEMBRANE SUPPORT FOR DRIP CHAMBER

FIELD OF THE INVENTION

The present invention relates generally to drip chambers used with intravenous infusion sets and particularly to membrane supports for such drip chambers.

BACKGROUND OF THE INVENTION

Intravenous infusion sets commonly include drip chambers (DCs) to enable the flow rate of an infusion liquid to be visually observed. In a typical installation, an infusion bag is suspended above a patient and a spike at an inlet of the DC pierces the bag, whereby the infusion liquid drips into the DC. The flow rate of the infusion liquid may be observed by the rate of formation of drops of the liquid from the inlet into the DC down through an outlet of the DC which is connected to tubing to the patient. The DC helps prevent air from entering the downstream tubing. This is achieved by a liquid layer acting as an air barrier at the bottom of the chamber. It is formed by manual "priming" (squeezing) of the chamber before the start of infusion.

Commercial drip chambers are constructed simply of a flexible, transparent cylinder with inlet and outlet. They also often contain a screen at the bottom, acting as a coarse filter preventing particles from entering the vein.

It is desirable to have a finer filter such as a hydrophilic membrane, ideally a bacteria retentive membrane, incorporated into the DC. This is advantageous in that it obviates the use of an extra filter often connected downstream of the infusion set. More importantly, such a membrane has the advantage of solving the following problem often encountered in infusion. When the infusion bag empties, so does the DC. As the above mentioned liquid layer is now absent, air enters the tubing downstream of the DC. This necessitates opening the system and repriming the set before infusion can be continued. By using a hydrophilic membrane at the DC outlet, liquid flow is not impeded, yet air intrusion is substantially prevented at all pressures below the membrane "bubble point". Thus after the infusion bag empties a new bag can be connected and infusion restarted without need for repriming.

A few patents (e.g. US 4,013,072, US 4,521,212 and US 5,902,281 assigned to the applicant/assignee, the disclosures of which are incorporated herein by reference) have described infusion devices that include membranes, however no simple, membrane-based infusion set is available commercially. The reasons for this are both technological and commercial. Membranes are sensitive structures and may easily be affected by solvents, glues and other bonding means. Also, infusion sets need to conform to certain flow and accuracy

criteria which may be affected by the membrane. Additionally the infusion set must remain inexpensive even with the membrane incorporated.

Another infusion device with a membrane is described in US Patent 5,779,674 to Ford. In this device, a hydrophilic membrane is attached to a support structure and may be horizontally or vertically oriented. However, this device has a drawback of the membrane being situated close to a base which is bonded with an adhesive to a drip chamber, meaning that the membrane can possible come into contact with the adhesive. In addition, the structure of the membrane support is such that air entrapped downstream of the membrane, between the membrane and drip chamber outlet, can occasionally escape into the infusion line, thus defeating the whole purpose of the membrane drip chamber.

The need therefore exists for an economical, accurate, high throughput, membrane-containing drip chamber that poses no danger of air escaping into the infusion line.

SUMMARY OF THE INVENTION

The present invention seeks to provide an improved membrane support that permits safe mounting of a membrane, e.g., a hydrophilic or bacterially retentive membrane, into a drip chamber with no danger of contaminating or ruining the membrane with adhesive and the like. The membrane support includes a support member that supports the membrane at a safe distance from ends of the support member which are bonded to the drip chamber with adhesive. In one embodiment, the membrane is generally perpendicular to a longitudinal axis of the drip chamber. In another embodiment, the membrane is generally parallel to the longitudinal axis. The latter embodiment permits using a membrane with a significantly larger surface area and is particularly useful for a bacterially retentive membrane.

There is thus provided in accordance with a preferred embodiment of the present invention a membrane support for assembly into a drip chamber, including a support member having a longitudinal axis, two ends and at least one support face distanced from both ends and generally parallel to the longitudinal axis, a membrane joined to the at least one the support face, and a support member outlet formed in the support member and in fluid communication with the membrane, the support member outlet being fluidly communicable with an outlet of a drip chamber.

In accordance with a preferred embodiment of the present invention a drain outlet is located at an upper portion of the support member, the support member being formed with a conduit which fluidly connects the drain outlet to the support member outlet.

Further in accordance with a preferred embodiment of the present invention the membrane support is bonded to a drip chamber with an adhesive, the adhesive not contacting the membrane.

Still further in accordance with a preferred embodiment of the present invention the membrane has a surface area of at least about 5 cm^2. The support member outlet may be connectable to downstream tubing of an infusion set.

There is also provided in accordance with a preferred embodiment of the present invention a membrane support for assembly into a drip chamber, including a support member having a longitudinal axis, two ends and at least one support face distanced from both ends, a membrane joined to the at least one the support face, and a drain outlet located at an upper portion of the support member.

There is also provided in accordance with a preferred embodiment of the present invention a membrane support for assembly into a drip chamber, including a support member including an open-ended cylinder having a longitudinal axis, two ends and at least one support face distanced from both ends, generally perpendicular to the longitudinal axis, the at least one support face extending inwards from an inner wall of the cylinder and having a peripheral rim, a membrane joined to the peripheral rim of the at least one the support face, and an outlet formed in the support member and in fluid communication with the membrane, the outlet being formed with a bore and being fluidly communicable with an outlet of a drip chamber.

In accordance with a preferred embodiment of the present invention the membrane support is bonded to a drip chamber with an adhesive, the adhesive not contacting the membrane. Preferably the membrane is hydrophilic, and may be bacterially retentive.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

Fig. 1 is a simplified pictorial illustration of a membrane support and drip chamber, constructed and operative in accordance with a preferred embodiment of the present invention; and

Figs. 2 and 3 are simplified pictorial and cutaway illustrations, respectively, of a membrane support constructed and operative in accordance with another preferred embodiment of the present invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Reference is now made to Fig. 1 which illustrates a drip chamber 5 and membrane support 10, constructed and operative in accordance with a preferred embodiment of the present invention.

Membrane support 10 includes a support member 7 preferably constructed of a short, open-ended cylinder with a central, generally circular support surface 12, most preferably integrally formed therewith, such as by injection molding. Support member 7 has a longitudinal axis 8 and two ends 9.

Support surface 12 extends inwards from an inner wall of the support member 7 at a distance from both ends 9. Support surface 12 may be slightly conical in shape, although it is appreciated that any arbitrary shape may be used. Support surface 12 preferably has a peripheral rim 14 to which a generally circular membrane 16 (shown partially in Fig. 1) can be joined. As used herein, reference to two materials or elements being "joined" refers to the situation wherein the two materials or elements are directly joined to one another or where they are indirectly joined to one another such as where both are joined to an intermediate element. Similarly, methods of joining two materials or elements include forming the elements or materials integrally, or attaching the elements together such as through the use of sonic or thermal bonding, welding, and the like.

An outlet 11 preferably extends from support surface 12 and is formed with a bore 18. Outlet 11 is connectable to downstream tubing (not shown) of an infusion set (not shown). Membrane support 10 is preferably bonded to DC 5 by applying a small amount of adhesive to a bottom surface 19 of DC 5. The adhesive is never in close contact with membrane 16 and possible damage is minimized.

DC 5 is connected to an infusion bag (not shown) in the usual manner. When DC 5 is first primed, membrane 16 wets within a few seconds. Thereafter air cannot escape DC 5 at pressures below the bubble point of membrane 16. This bubble point pressure varies according to membrane pore size and can be chosen over a wide range, for example 0.05-5 atm. For a typical infusion set use, a bubble point pressure of 0.5-1 atm. will be suitable, corresponding to a pore size rating of 1-5μm.

Upon emptying of the infusion bag, liquid level in DC 5 will recede and reach exactly the height of membrane 16. No air will penetrate below membrane 16. Thus the downstream infusion line will remain primed. A new bag can, therefore, be connected upstream of DC 5 and infusion continued with no need for repriming.

In another embodiment of the invention, membrane 16 may be a bacterially retentive membrane. Such membranes have a pore size rating of 0.2 μm and below and are capable of retaining most known bacteria even at high volume concentration. Such a membrane can be built into DC 5 with its generally circular configuration, as described above. However, this configuration is generally not suitable for bacterially retentive membranes, because such membranes are quite "tight" and therefore provide relatively low liquid throughputs. The surface area provided by the circular configuration (about 1 cm^2) is too small for either gravity or pump driven infusion.

Reference is now made to Figs. 2 and 3 which illustrate a membrane support 20 constructed and operative in accordance with another preferred embodiment of the present invention. In membrane support 20, the membrane area is substantially increased by arranging the membrane surface generally parallel to the DC longitudinal axis, instead of perpendicular as in the embodiment of Fig. 1, as is now described. The increased membrane area is a significant advantage because it enables use of bacterially retentive membranes with good liquid throughputs.

Membrane support 20 preferably includes an upright, generally rectangular support member 22 with a generally circular base 24. A membrane 26 is joined to one or both large support faces of support member 22. A membrane surface area of 5-7 cm^2 can easily be achieved in this embodiment. The membrane surface is generally parallel to a longitudinal axis 27 of membrane support 20 and a drip chamber (not shown). A drain outlet 28 (Fig. 3) is preferably located at an upper portion of support member 22 in order to drain all air from the downstream volume of support member 22. Filtrate can flow from drain outlet 28 via a conduit 30 to an outlet 32. Outlet 32 is preferably formed with a bore 33 and is connectable to downstream tubing (not shown) of an infusion set (not shown). As similarly described above for the embodiment of Fig. 1, membrane support 20 is preferably bonded to a DC (not shown) by applying a small amount of adhesive to a bottom surface of the DC. The adhesive is never in close contact with membrane 26 and possible damage is minimized.

Using the configuration of Figs. 2 and 3, high gravity infusion flow rates are achievable. In pump driven infusion, little effect on pump accuracy is seen.

The configuration of Figs. 2 and 3 has an additional advantage. Standard DC's are limited to an upright configuration. Turning the DC upside down will cause the trapped air to dangerously escape into the infusion line, and infusion fluid to fill the DC completely. The

embodiment of Fig. 1 can prevent air loss. However that embodiment will not function in an upside-down orientation because air will contact the air-impermeable membrane 16.

In contrast, the embodiment of Figs. 2 and 3 prevents air escape and functions in all orientations. When properly primed, liquid will be in contact with membrane 26 in both the upright and turned-over configurations. This DC is therefore suitable also for emergency use, where an upright orientation cannot always be assured.

Two examples of tests performed with the above described embodiments are now described.

Example 1. Gravitational Flow Rate

A membrane-containing drip chamber (MDC) was constructed in accordance with the embodiment of Fig. 1. An 8 μm rated nitrocellulose membrane was welded into the cylindrical insert. The MDC was incorporated in a standard infusion set. The gravitational flow rate was measured by connecting the set to an infusion bag containing saline and setting the outlet 1 m below the bag.

Flow rate ranged between 125 ml/min and 160 ml/min. The rate remained above 100 ml/min after 5 months of aging at 50^{0}C. This rate conforms to International Standard for Infusion Equipment ISO 8536-4 (1998).

In order to test prevention of air intrusion, the set was opened to the atmosphere. No air leaked into the downstream line for at least 8 hours.

Example 2. Bacterial Challenge

An MDC was constructed in accordance with the embodiment of Figs. 2 and 3, using a 0.2 μm rated polysulfone membrane. Minimum bubble point was measured by incorporating the drip chamber in an infusion set, priming it with saline and allowing excess liquid to drain by gravity. The MDC with wetted membrane was then pressurized by air to 2 atm. No air was detected at the outlet, indicating a bubble point higher than 2 atm. The MDC was then challenged with a bacteria suspension by aseptically connecting the set to an infusion bag containing sterile saline. An inoculum of pseudomonas diminutal was injected through the injection site so that the final concentration was 10^6 CFU/ml. The whole bag (100 ml) was then drained through the MDC into an empty, sterile bag. The receiving bag was then tested for sterility. No CFU's were detected.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the present invention includes both combinations and subcombinations of the features

described hereinabove as well as modifications and variations thereof which would occur to a person of skill in the art upon reading the foregoing description and which are not in the prior art.

CLAIMS

What is claimed is:

1. A membrane support (10, 20) for assembly into a drip chamber (5), characterized by:

a support member (7) having a longitudinal axis (8, 27), two ends (9) and at least one support face distanced from both ends (9) and generally parallel to the longitudinal axis (8, 27);

a membrane (16, 26) joined to said at least one said support face; and

a support member outlet (11, 32) formed in said support member (7) and in fluid communication with said membrane (16, 26), said support member outlet (11, 32) being fluidly communicable with an outlet of a drip chamber (5).

2. The membrane support (10, 20) according to claim 1 and further comprising a drain outlet (28) located at an upper portion of said support member (7), said support member (7) being formed with a conduit which fluidly connects said drain outlet (28) to said support member outlet (11, 32).

3. The membrane support (10, 20) according to claim 1 and further comprising a drip chamber (5), said membrane support (10, 20) being bonded to said drip chamber (5) with an adhesive, said adhesive not contacting said membrane (16, 26).

4. The membrane support (10, 20) according to claim 1 wherein said membrane (16, 26) is hydrophilic.

5. The membrane support (10, 20) according to claim 1 wherein said membrane (16, 26) is bacterially retentive.

6. The membrane support (10, 20) according to claim 1 wherein said membrane (16, 26) has a surface area of at least about 5 cm^2.

7. The membrane support (10, 20) according to claim 1 wherein said support member outlet (11, 32) is connectable to downstream tubing of an infusion set.

8. A membrane support (10, 20) for assembly into a drip chamber (5), characterized by:

a support member (7) having a longitudinal axis (8, 27), two ends (9) and at least one support face distanced from both ends (9);

a membrane (16, 26) joined to said at least one said support face; and

a drain outlet (28) located at an upper portion of said support member (7).

9. The membrane support (10, 20) according to claim 8 and further comprising a support member outlet (11, 32) formed in said support member (7) and in fluid communication with said membrane (16, 26), said support member outlet (11, 32) being fluidly communicable with

an outlet of a drip chamber (5), and wherein said support member (7) is formed with a conduit which fluidly connects said drain outlet (28) to said outlet.

10. The membrane support (10, 20) according to claim 8 and further comprising a drip chamber (5), said membrane support (10, 20) being bonded to said drip chamber (5) with an adhesive, said adhesive not contacting said membrane (16, 26).

11. The membrane support (10, 20) according to claim 8 wherein said membrane (16, 26) is hydrophilic.

12. The membrane support (10, 20) according to claim 8 wherein said membrane (16, 26) is bacterially retentive.

13. The membrane support (10, 20) according to claim 8 wherein said membrane (16, 26) has a surface area of at least about 5 cm^2.

14. The membrane support (10, 20) according to claim 8 wherein said support member outlet (11, 32) is connectable to downstream tubing of an infusion set.

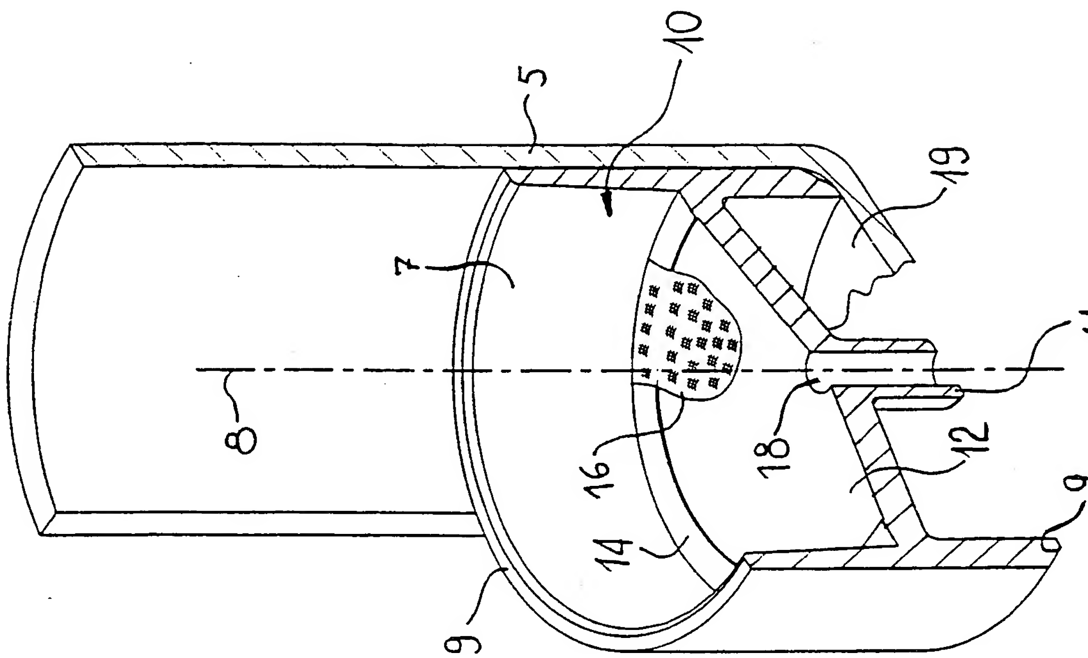
15. A membrane support (10, 20) for assembly into a drip chamber (5), characterized by:

a support member (7) comprising an open-ended cylinder having a longitudinal axis (8, 27), two ends (9) and at least one support face distanced from both ends (9), generally perpendicular to the longitudinal axis (8, 27), said at least one support face extending inwards from an inner wall of said cylinder and having a peripheral rim;

a membrane (16, 26) joined to said peripheral rim of said at least one said support face; and

an outlet formed in said support member (7) and in fluid communication with said membrane (16, 26), said outlet being formed with a bore and being fluidly communicable with an outlet of a drip chamber (5).

FIG. 1



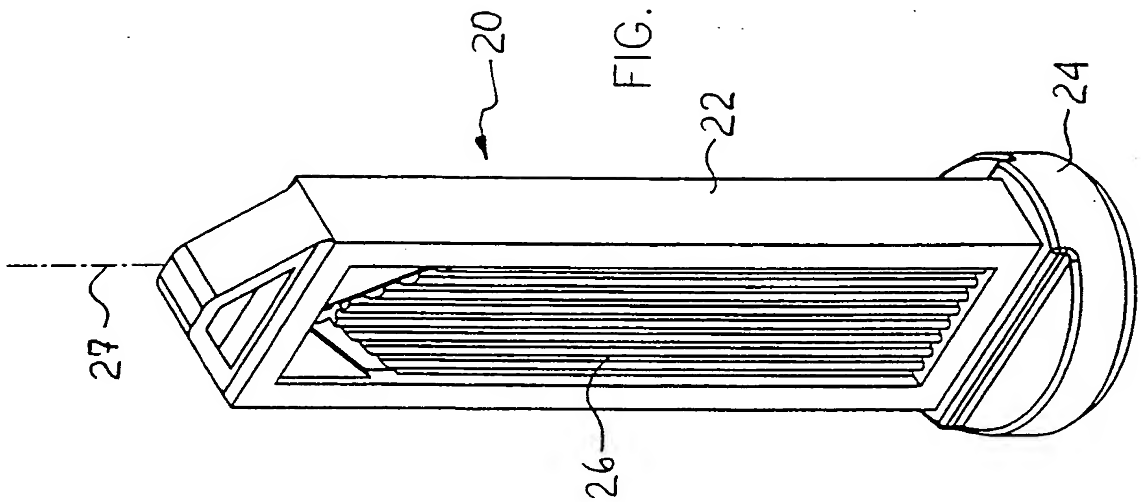


FIG. 2

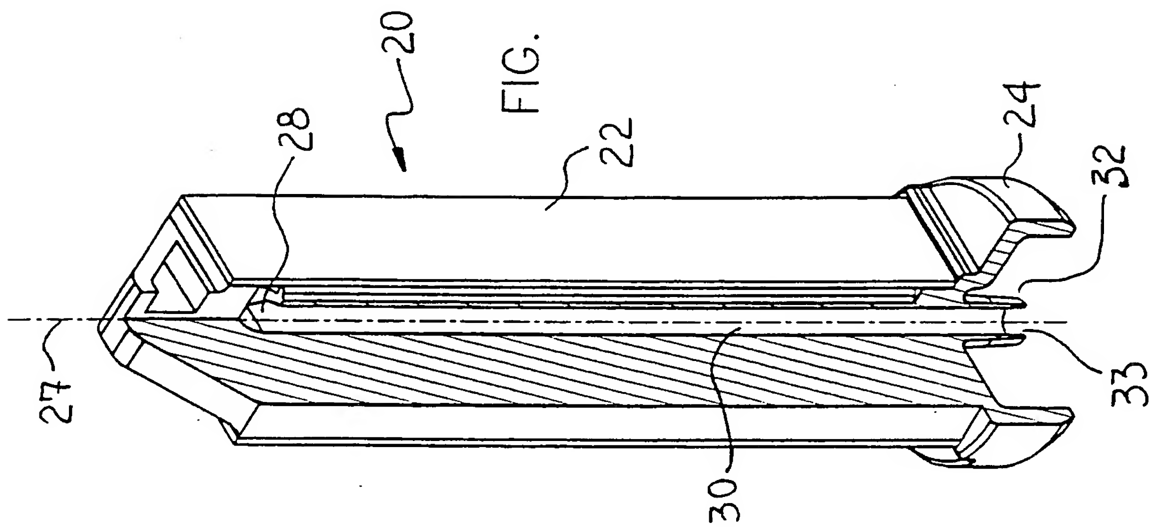


FIG. 3

INTERNATIONAL SEARCH REPORT

Intern. ıal Application No
PCT/IL 00/00560

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/38 A61M5/165

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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Date of the actual completion of the international search	Date of mailing of the international search report
22 November 2000	04/12/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Jameson, P

INTERNATIONAL SEARCH REPORT

International Application No
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